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10/589,396	08/15/2006	Hidenori Yoshida	294829US0PCT	8201

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EXAMINER	
WELTER, RACHAEL E	
ART UNIT	**PAPER NUMBER**
1611	

NOTIFICATION DATE	DELIVERY MODE
02/09/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/589,396	YOSHIDA ET AL.	
	Examiner	Art Unit	
	RACHAEL E. WELTER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5 and 7-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5 and 7-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/11/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 2-5 and 7-25 are pending. Claim 6 is cancelled. Claims 9-25 are newly added.

Acknowledgements

Receipt of the amendment and remarks/arguments filed on 12/8/10 is acknowledged.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on November 11, 2010 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. Accordingly, the information disclosure statement was considered by the examiner. A signed copy of form 1449 is enclosed herewith.

Withdrawn Rejections

The rejection of claims 1, 3, and 5-8 rejected under 35 U.S.C. 102(b) as being anticipated by JP 11-199456 (Published 7/27/1999; Translation provided herein) is withdrawn in light of applicant's amendments.

The rejection of claims 1, 3, and 6-8 rejected under 35 U.S.C. 103(a) as being unpatentable over Koichi et al (JP 2003-081796; Published 3/19/2003; see translation provided by applicant in IDS of 9/3/09) is withdrawn in light of applicant's amendments.

The rejection of claim 5 rejected under 35 U.S.C. 103(a) as being unpatentable over Koichi et al (JP 2003-081796; Published 3/19/2003; see translation provided by applicant in IDS of 9/3/09) as applied to claims 1, 3, and 6-8 above and in further view of JP 11-199456 (Published 7/27/1999; Translation provided herein) is withdrawn in light of applicant's amendments.

New Rejections

The following rejections constitute new grounds for rejection necessitated by amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-3, 5, 7-17, and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 11-199456 (Published 7/27/1999) in view of Satoshi et al (JP 01-299211; Published 12/4/1989; Abstract Only).

JP '456 discloses a toothpaste composition with 0.5 wt.% crystalline cellulose powder with a particle size of 60 um, 30 wt.% calcium hydrogen phosphate anhydrate as an abrasive, saccharin sodium as a sweetener, approximately 21 wt.% water, and sodium lauryl sulfate as a surfactant (paragraph 0031). Exemplified RDA values were 40, 42, 90, 130, 115, and 110 (see Table 2). Surfactants in the composition include both nonionic and anionic (paragraph 0013). One or two binders are exemplified in the compositions including 0.5 wt.% carrageenan, 0.7 wt.% xanthan gum (paragraph 0029). Moisturizers or humectants can also be incorporated in the compositions including propylene glycol exemplified in an amount of 3 wt.% (paragraph 0012; paragraph 0031).

JP '456 does not teach compositions with granules having a particle size permitting passage of a 30-mesh sieve but not permitting passage of a 200-mesh sieve.

The Japanese Office Action of 11/10/09 translates JP 01-299211. According to the Office Action and abstract of JP '211, the reference teaches granules having a particle size passing through a 30 mesh sieve but incapable of passing through a 200 mess sieve in a dentrifice composition. The granules are added to increase abrasive power (see pg. 3 of Office Action) and are obtained by granulating a water-insoluble powdery material with a water-insoluble inorganic binder (abstract). Additionally, the granules have disintegration strength when 0.1 to 10 g of a load is applied per granule (abstract).

Therefore, it would have been obvious to an artisan at the time the invention was made to add such granules to the oral/toothpaste composition of JP '456. One would have been motivated to do so in order to add more abrasive power to the compositions as suggested in JP '211. Since the compositions of JP '456 desire compositions with abrasives, an artisan of ordinary skill would have been motivated to add more abrasives with the expectation that such an addition could result in a complementary or possibly synergistic effect. Furthermore, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (*see MPEP 2144.06*).*

Regarding the limitation of claim 5, wherein the powder cellulose is a non-granulated powder, JP '456 does not teach or suggest that its cellulose is granulated.

However, the cellulose's particle size of JP '456 anticipates the instant particle size. As such, it is the examiner's position that the powder is non-granulated unless applicant proves otherwise.

Regarding the amount of granules incorporated in the composition (instant claim 12), it is the examiner's position that it would have been obvious to an artisan of ordinary skill to incorporate a similar amount of granules as JP '456's abrasive, calcium hydrogen phosphate anhydrate. One would have been motivated to do so since JP '211 teaches that its granules are also used to increase abrasive power. Furthermore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to manipulate and optimize the amounts of granules because methods of determining appropriate component percentages are well-known in the art, and one of skill in the art would have arrived at the appropriate percentages via routine experimentation. Manipulation of relative amounts of formulation components do not support the patentability of subject matter encompassed by the prior art, unless there is evidence indicating unexpected results.

Claims 2-3, 7-20, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koichi et al (JP 2003-081796; Published 3/19/2003; see translation provided by applicant in IDS of 9/3/09) in view of Satoshi et al (JP 01-299211; Published 12/4/1989; Abstract Only) as evidenced by "HLB Values," http://www.chemicalland21.com/info/HLB_VALUES.htm.

Koichi et al teach a composition for the oral cavity that prevents coloration of the teeth comprising a first abrasive having an RDA of 130-200 and a second abrasive having an RDA of 40-110 (claims 5 and 7). The first abrasive is in an amount of 0.5-10 wt.% and the second abrasive is in an amount of 3-25 wt.% (paragraphs 0022, 0029). The composition also comprises a surfactant (claim 1) and can include powder state cellulose in an amount of 0.1-30 wt.% and preferably 0.5-10 wt.% (paragraph 0037). Binders in the composition include sodium alginate, carrageenan, xanthan gum and sodium carboxymethylcellulose in an amount of 0.3-5 wt.% (paragraph 0041). The binders may be used independently or two or more can be mixed. Surfactants in the composition include both anionic and nonionic in amounts of 0.001-5 wt.% (paragraphs 0038-0039). Anionic surfactants include acyl amino acid salts and nonionic surfactants include polyoxyethylene sorbitan monolaurate and polyoxyethylene (60) hydrogenated castor oil among others (paragraph 0039; paragraph 0065). As evidenced by HLB, POE sorbitan monolaurate has a HLB of 16.9 and POE (60) hydrogenated castor oil has a HLB of 14 (pg. 2). Sweetening agents such as saccharin sodium can be included in the composition as well as humectants, glycerin and propylene glycol in amounts of 5-70 wt.% (paragraphs 0043-0044). Additionally, Koichi et al disclose that the pH of its compositions is usually 4-10 (paragraph 0045). Water can be incorporated in the compositions in an amount of 10-50 wt% (paragraph 0035).

Koichi et al do not teach compositions with granules having a particle size permitting passage of a 30-mesh sieve but not permitting passage of a 200-mesh sieve.

The Japanese Office Action of 11/10/09 translates JP 01-299211. According to the Office Action and abstract of JP '211, the reference teaches granules having a particle size passing through a 30 mesh sieve but incapable of passing through a 200 mess sieve in a dentrifice composition. The granules are added to increase abrasive power (see pg. 3 of Office Action) and are obtained by granulating a water-insoluble powdery material with a water-insoluble inorganic binder (abstract). Additionally, the granules have disintegration strength when 0.1 to 10 g of a load is applied per granule (abstract).

Therefore, it would have been obvious to an artisan at the time the invention was made to add such granules to the oral/toothpaste composition of Koichi et al. One would have been motivated to do so in order to add more abrasive power to the compositions as suggested in JP '211. Since the compositions of Koichi et al desire compositions with abrasives, an artisan of ordinary skill would have been motivated to add more abrasives with the expectation that such an addition could result in a complementary or possibly synergistic effect. Furthermore, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (*see MPEP 2144.06*).*

Regarding the amount of granules incorporated in the composition (instant claim 12), it is the examiner's position that it would have been obvious to an artisan of

ordinary skill to incorporate a similar amount of granules as Koichi's abrasives. One would have been motivated to do so since JP '211 teaches that its granules are also used to increase abrasive power. Additionally, it would have been obvious to manipulate and optimize the amount of nonionic surfactant to anionic surfactant in Koichi's composition. Koichi generally teaches that a surfactant should be incorporated in an amount of 0.001-5 wt.% (paragraph 0038). Methods of determining appropriate component percentages are well-known in the art, and one of skill in the art would have arrived at the appropriate percentages via routine experimentation. Manipulation of relative amounts of formulation components do not support the patentability of subject matter encompassed by the prior art, unless there is evidence indicating unexpected results.

Claims 5 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koichi et al (JP 2003-081796; Published 3/19/2003; see translation provided by applicant in IDS of 9/3/09) in view of Satoshi et al (JP 01-299211; Published 12/4/1989; Abstract Only) as applied to claims 2-3, 7-20, and 22-25 above and in further view of JP 11-199456 (Published 7/27/1999) as evidenced by "HLB Values," http://www.chemicalland21.com/info/HLB_VALUES.htm.

The disclosures of Koichi et al and Satoshi et al are discussed above.

Koichi et al and Satoshi et al do not teach the instant particle size of powder cellulose.

JP ‘456 discloses a toothpaste composition with 0.5 wt.% crystalline cellulose powder with a particle size of 60 um, 30 wt.% calcium hydrogen phosphate anhydrate as an abrasive, and sodium lauryl sulfate as a surfactant (paragraph 0029) Exemplified RDA values were 40, 42, 90, 130, 115, and 110 (see Table 2). One or two more binders are exemplified in the compositions including carrageenan and xanthan gum (paragraph 0029). According to JP '456 a desirable mean particle size of powder cellulose is 70-150 um (paragraph 0005). JP '456 teaches that powder cellulose smaller than 50 um will not achieve sufficient cleaning powder and particle sizes larger than 200 um will be both undesirable and uncomfortable for the consumer.

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to incorporate the instant particle size of powder cellulose in the oral cavity composition of Koichi et al. One would have been motivated to do so since JP '456 suggests that such a particle size is desired because it provides sufficient cleaning and more comfort for the consumer.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koichi et al (JP 2003-081796; Published 3/19/2003; see translation provided by applicant in IDS of 9/3/09) or JP 11-199456 (Published 7/27/1999) in view of Satoshi et al (JP 01-299211; Published 12/4/1989; Abstract Only) and in further view of Hiroaki et al (JP 09-295947; Published 11/18/1997; Translation provided by applicant in IDS of 9/3/09) as evidenced by “HLB Values,” http://www.chemicalland21.com/info/HLB_VALUES.htm.

The disclosures of Koichi et al and JP ‘456 are discussed above.

The average polymerization degree of powder cellulose in Koichi or JP '456 is not clear. The average polymerization degree may be the same as claimed. JP '456 teaches that its powder cellulose has a fixed degree of polymerization (paragraph 0005). However, neither JP '456 nor Koichi explicitly teach powder cellulose having an average polymerization degree of 440-2250.

Hiroaki et al teach microspherical particles with a diameter of 0.08-1 mm containing at least 10 wt.% powdered cellulose with an average degree of polymerization of 380-2500 (claim 1). The microspherical particles are useful as vehicles for pharmaceuticals and food products (paragraph 0001). According to Hiroaki, a common commercially available product of cellulose powder exhibits a preferable average polymerization degree of 440-2250 (paragraph 0014).

Although Koichi or JP '456 do not specify the average polymerization degree of powder cellulose, which may be taught in the references, it would have been obvious to an artisan of ordinary skill at the time the invention was made to look at the teachings of Koichi or JP '456 and expect the powder cellulose to have the instant average polymerization degree. One would have expected this since Hiroaki teaches that a common commercially available product of powder cellulose used in pharmaceutical/food compositions exhibits the instant average polymerization degree (preferably 440-2250). Furthermore, one would have been motivated to manipulate the powder cellulose of Koichi or JP '456 to have the instant polymerization degree because Hiroaki suggests that powder cellulose with the instant polymerization degree is conventional in pharmaceuticals and food products.

Response to Arguments

Applicant's arguments filed 12/8/10 have been fully considered but they are not persuasive.

Applicant argues that the claimed composition provides for enhanced foaming performance. Applicant conducted additional testing, submitted in the Declaration by Mr. Yoshida. Toothpaste compositions were prepared but with variations in the content and nature of surfactant and silica granules. The foaming quality and quantity was analyzed using the techniques reported in example 15 of the specification. According to applicant, the data provides evidence of an enhancement in foaming quantity and quality for the combination of surfactant, powdered cellulose and silica of specified size. Applicant tested surfactant in amounts of 1.5-4.5 wt.% and silica granules ranging from 2.5-25.5 wt% with particle size ranges of 100-200 um. Applicant submits that the cited art fails to have combined the three claimed components and fails to identify any effect on foaming from dentrifice granules.

The Rule 132 Declaration under 37 CFR 1.132 by Mr. Yoshida is insufficient to overcome the rejection of the claims because:

It is the examiner's position that a prima facie case of obviousness has been established. It would have been obvious to select and incorporate the instant granules of JP '211 into the composition of Koichi/JP '456 for the reasons stated in the rejection above, which are incorporated herein. As such, it is the examiner's position that applicant's alleged unexpected results would have been an obvious intrinsic property of the prior art. "The fact that applicant has recognized another advantage which would

flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979).

Additionally, it is noted that applicant's additional evidence is not commensurate in scope with the instant claims. According to MPEP 716.02, whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." Independent claim 2 generically claims any surfactant, powder cellulose, and any granule of specific size in any amount. On the other hand, applicant only tested anionic and nonionic surfactants in amounts from 1.5- 4.5 wt.% and silica granules ranging from 2.5-25 wt.% with a particle size range of 100-200 um. Merely showing three specific types of surfactants and silica granules in specific amounts does not meet the larger scope of independent claim 2. One cannot extrapolate three specific surfactants and granules to each and every compound that falls within the broad, generic categories of the components in the instant claims. As such, in order to commensurate the scope of the instant claims with applicant's alleged unexpected evidence; applicant needs to narrow the scope of the instant claims.

Lastly, it is noted that the foam quality of applicant's compositions were assessed by a panel of 5 experts (see instant specification pg.24) and are opinion based.

"Although an affidavit or declaration which states only conclusions may have some probative value, such an affidavit or declaration may have little weight when considered in light of all the evidence of record in the application." Since such results were simply rated by experts and are unsupported by objective factual evidence, the results will be considered as having little evidentiary value. Furthermore, it is not necessarily clear what assessment scores are desirable for superior foam. For example, it is not clear if finer foams are desired, if viscous foams are desired, if elastic foams are desired, etc. Without this knowledge, it is difficult to determine if there is actual enhancement in foaming quality of the instant invention. Applicant's clarification is respectfully requested.

Thus, absent any sufficient unexpected results, it is the examiner's position that the rejections should be maintained for the reasons stated above.

Conclusion

Claims 2-5 and 7-25 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/David J Blanchard/
Primary Examiner, Art Unit 1643